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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/549,036	04/13/2000	Gregory A Farrell	MST-2322.1	7845

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EXAMINER

HANDY, DWAYNE K

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/549,036

Applicant(s)

FARRELL, GREGORY A

Examiner

Dwayne K. Handy

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

1. The amendment filed 1/6/2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows: Applicant has claimed a magnetic detection means in claim 27. Since no elements of this system were ever disclosed in the specification, however, one skilled in the art could not be enabled to make and/or use the invention.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has claimed a magnetic detection means in claim 27. Since no elements of this system were ever disclosed in the

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specification, however, one skilled in the art could not be enabled to make and/or use the invention.

Inventorship

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 23, 24, 26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bezanson (5,106,187) in view of Sklar et al. (5,895,764). The Examiner believes applicant is familiar with this rejection since this rejection was previously applied to claims 18-22. The rejection is repeated for applicant's convenience below:

Bezanson teaches a method and an apparatus for particle identification. Bezanson's teachings disclose every element of applicant's method except for teaching a sheath fluid which is delivered in laminar flow. Bezanson recites delivering sample and sheath fluid streams (col. 2, lines 11-23), drawing the sample into a suspension stream of fixed diameter (col. 2, lines 13-14), and detecting a characteristic of the sample (col. 2, lines 38-42). Bezanson later recites use of computer to analyze signals and compare the signals to preset limits. The results from the analysis are then used to control the operation of the valves and pumps within the system (Figure 3, also col. 3, lines 37-65). As to the limitations of claims 19 and 20, Bezanson discloses detection of particles and particle mixtures in the abstract and invention summary and in claim 2. Finally, Bezanson teaches controlling the pumping rates for optimal characteristic detection (waveform resolution) in column 3, lines 24-28. Sklar et al. discloses a method for controlled sheath flow cytometry. Their method also includes delivering the sample in a suspension stream which includes a sheath flow. Furthermore, the sheath flow is controlled to yield stable laminar flow (col. 3, lines 25-27 and 60-67). Sklar then teaches why they control the sheath flow to yield a laminar flow stream at the top of column 4. Sklar states "When the normal laminar flow is perturbed, some beads will not flow through the optimal laser focus point and will be measured with a reduced fluorescence". It would have been obvious to one of ordinary skill in the art then, to combine the teaching of the use of a laminar sheath flow when using a flow cell in order to insure an accurate reading of the particles flowing through the cell. Both Sklar et al. and Bezanson use flow cells to analyze the particles which are present in the sample. The use of laminar sheath flow would yield better results when combined with the method of Bezanson.

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7. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bezanson (5,106,187) and Sklar et al. (5,895,764), and further in view of Yamamoto et al. (5,488,469). Bezanson and Sklar, as combined above in paragraph 6, teach every element of claim 25 except for the analysis of a hematology sample. Both Bezanson and Sklar recite samples having cells, but not blood samples specifically. Yamamoto also teaches a cell counting apparatus. Yamamoto teaches use of the apparatus in the analysis of blood samples (column 4, lines 45-66; column 5, line 65; column 8, line 48-53). It would have been obvious to combine the examination of a blood sample with the combined teachings of Bezanson and Sklar. One would examine a blood sample with the combined device of Bezanson and Sklar to take advantage of the features provided - including an improved count of the cells in the sample.

Response to Arguments

8. Applicant's arguments filed 1/6/2005 have been fully considered but they are not persuasive. In traversing the rejection made by the Examiner in the previous action, applicant appears to be relying on two main arguments: (1) Bezanson does not teach the steps of applicant's method; and (2) The addition of Sklar does not make up for the shortcomings of Bezanson. The Examiner respectfully disagrees. As noted above, Bezanson does indeed teach a method which includes all of applicant's steps except for the use of laminar flow. Bezanson delivers both a sample and sheath streams that are configured so that only one particle passes through the sensing zone at one time (col. 2, lines 11-25), Bezanson measures the particle or cell count (col. 2, lines 38-42), and

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then adjusts the flow rate accordingly based on a comparison of the measured cell count with preset limits (col. 3, lines 19-46 and claim 11). This adjustment optimizes the signal received from the sensing zone and the ability of the detection machine (column 3, lines 25-28).

9. As to the addition of Sklar, the Examiner is not relying on Sklar for the adjustment steps as suggested by applicant in the submitted arguments (page 7, lines 6-18).

Instead, the Examiner is relying on Sklar for a teaching of the use of laminar flow.

Applicant has also contended that Sklar does not have any application to the claimed

invention. The Examiner reminds applicant that, it has been held that a prior art

reference must either be in the field of applicant's endeavor or, if not, then be

reasonably pertinent to the particular problem with which the applicant was concerned,

in order to be relied upon as a basis for rejection of the claimed invention. See *In re*

Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the Examiner

is relying on a teaching of the use of laminar flow in a cell counting system. Sklar states

that the use of laminar flow is useful to insure focused measurement of a mixed sample

and reactant (column 4 and claim 1). Improving the focus of the detection device to

yield a more accurate measurement of the particles being examined is a field that is

reasonably pertinent to the field of cell counting. Therefore, the Examiner believes one

of ordinary skill in the art would indeed be motivated to combine Sklar with Bezanson.


Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DKH
May 27, 2005


Jill Warden
Supervisory Patent Examiner
Technology Center 1700